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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,807	04/13/2006	Yaeta Endo	3190-096	3895
33432	7590	09/30/2008		
KILYK & BOWERSOX, P.L.L.C. 400 HOLIDAY COURT SUITE 102 WARRENTON, VA 20186			EXAMINER	
			COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	
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09/30/2008	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,807	<b>Applicant(s)</b> ENDO ET AL.
	<b>Examiner</b> LISA V. COOK	<b>Art Unit</b> 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 July 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date 6/28/06 & 8/25/06

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of species I (**a** in claim 5), II (**e** in claims 7, 16, and 17) and III (**j** in claims 8, 18, and 19) with traverse in the reply filed on 7/14/08 is acknowledged. Applicant contends that no serious burden exists to search the entire scope of the claims. Applicant's arguments have been considered and found persuasive. The restriction requirement of record and mailed 6/26/08 is withdrawn.
  
2. Currently claims 1-19 are pending and under consideration.

### ***Information Disclosure Statement***

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.
  
4. The information disclosure statement filed 6/28/06 has been considered as to the merits before First Action.
  
5. The information disclosure statement filed 8/25/06 has been considered as to the merits before First Action.

***Specification***

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. The use of the trademarks has been noted in this application. (.i.e. SEPHADEX-page 42 and page 48, SEPHAROSE-page 46). They should be capitalized wherever they appear or accompanied by the <sup>TM</sup> or<sup>®</sup> symbol wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

II. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. In the instant application, the abstract in more than one paragraph. Appropriate correction is required.

III. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### ***Arrangement of the Specification***

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

8. In the instant application, the brief description of the drawings is located at the end of the disclosure on pages 48 and 49. They should follow the brief summary of the invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "passively" in claims 1 and 10 is a relative term which renders the claim indefinite. The term "passively" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what Applicant will consider a passively producing method thus reading on the instant claims. Please clarify.

B. In claim 1 is vague and indefinite because it is not clear as to what the method is being utilized for. Claim 1 step 2 recites "specifying the substance change". It is not clear what is meant by "specifying". Will the substance be detected and/or evaluated?

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 10 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

11. Claim 10, as written, do not sufficiently distinguish over the claimed biomarker as it exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Human proteins are products of nature.

In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

#### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-8 and 10-19 are rejected under 35 U.S.C. 103(a) as being obvious over Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of Kato et al. (US Patent #6,268,157).

Sawasaki et al. teach a cell-free protein synthesis system. The system is based on the eukaryotic translation apparatus of wheat seeds and allows for the screening and synthesis of gene products. See abstract. Wheat embryos and cell-free extracts were purified. See page 14652-Materials.

In one instance protein products were tested as functional enzymes in the wheat cell free system. Four of five proteins displayed autophosphorylation activity after incubation with [ $\gamma$ -<sup>32</sup>P]ATP and magnesium. See figure 5b.

Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) differ from the instant invention in not specifically teaching the inclusion of an indicator substance.

However, Kato et al. (US Patent #6,268,157) teach methods of screening pharmaceutical for various diseases. See column 1 lines 9-14 and column 4 line 65 through column 5 line 10. The use of these screening methods can specifically identify inhibitors and accelerators for use in disease treatments. See column 1 lines 40-47 and column 10 lines 47-53.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the screening assay of Sawasaki et al. to measure indicator substances as exemplified by Kato et al. because Kato et al. taught that use of these screening methods can specifically identify inhibitors and accelerators for use in disease treatments. See column 1 lines 40-47 and column 10 lines 47-53.

One of ordinary skill would have been motivated to measure indicator substances (like pharmaceuticals) in order to understand/evaluate the drugs effect various disease.

II. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of in view of Kato et al. (US Patent #6,268,157) and further in view of Foster et al. (U.S. Patent #4,444,879).

Please see Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of in view of Kato et al. (US Patent #6,268,157) as set forth above.

Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of in view of Kato et al. (US Patent #6,268,157) differ from the instant invention in not specifically teaching kit configurations.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of in view of Kato et al. (US Patent #6,268,157) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit.

Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

13. For reasons aforementioned, no claims are allowed.

***Remarks***

14. Prior art of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Madin et al. (Proceedings of the National Academy of Sciences, USA Vol.97, No.2, 1/18/00, pages 559-564) disclose the isolation of wheat embryos.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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